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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,127	03/06/2006	Christopher J. Montague Meade	09859/0203879-USO	8875
7278	7590	10/11/2007	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			PACKARD, BENJAMIN J	
			ART UNIT	PAPER NUMBER
			4173	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,127

Applicant(s)

MEADE ET AL.

Examiner

Benjamin J. Packard

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4500

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date (2 pages).

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of airway diseases, does not reasonably provide enablement for the prophylaxis of pulmonary diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

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The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In *re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to the prophylaxis of exacerbations associated with pulmonary diseases. The relative skill of those in the art is high, that of an MD or Ph.D.

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That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites Di Stefano et al, Cellular and molecular mechanisms in chronic obstructive pulmonary disease: an overview, Clinical & Experimental Allergy 34 (8), 1156–1167 (2004). Di Stefano teaches that test results vary due to the lack understanding of the pathway, making the diseases difficult to treat (See page 1165 third paragraph).

2. The breadth of the claims

Since the instant specification provides no limiting definition of the term “prophylaxis”, the examiner will adopt the broadest reasonable interpretation for same. Webster’s Ninth New Collegiate Dictionary defines “prophylaxis” as “prevent the spread of disease”, i.e., to completely prevent.

The claims are thus very broad insofar as they recite the “prophylaxis” of exacerbations associated with pulmonary diseases, i.e., the complete eradication of same. While such “prophylaxis” might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the “real world” in which patients live; exacerbations associated with pulmonary diseases is always a risk.

3. The amount of direction or guidance provided and the presence or absence of working examples

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The specification provides no direction or guidance for the prevention of exacerbations associated with pulmonary diseases. No reasonably specific guidance is provided concerning useful therapeutic protocols for recite the "prophylaxis" of exacerbations associated with pulmonary diseases.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6-8, 10-21, 25-28, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANHOLZER et al (US 5,610,163), in view of OHSHIMA, et al (US 6,514,996).

BANHOLZER et al teaches the anticholinergic of the instant claim 3, which reads on formula 1 and 1a from the instant claims 1 and 2 (see column 16 lines 30-54 and claim 5). BANHOLZER et al further teaches the use of the active ingredients for the treatment of respiratory tract diseases, such as asthma (column 3 lines 38-43) as well as the administration by inhalation solutions, suspensions or capsules (column 4 lines 3-9) when combined with common excipients (column 4 lines 3-4).

BANOLZER et al does not teach the addition of the instant compound of formula 2 or specific ranges.

OHSHIMA, et al teaches the use of the instant compound of formula 2 (see compound 140 at column 67 lines 1-15 and lines 50-55) for the use in treating asthma (column 294 lines 36-39) by administration through inhalation solutions, suspensions or capsules when combined with common excipients (see preparation examples 1-13 from column 292 line 5 to column 294 line 32).

Generally, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows

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logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069,1072 (CCPA 1980); In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). Conversely, there is no evidence in the record establishing that appellant's combination of agents is any more effective or in any way different than any single member of that combination. See In re Dial, 140 USPQ 244 (C.C.P.A. 1964). Here, both compounds are taught to treat asthma through the same means.

Additionally, it is prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation. See In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980); and In re Peterson, 65 USPQ2d 1379 (Fed. Cir. 2003).

Where properties are disclosed, such as pH, they are inherent properties of the combination. Therefore, one of ordinary skill in the art would expect the properties of the composition to be within the instantly claimed ranges when the compositions are identical.

Claims 1, 4-7, 9-21, 25-27, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over MEISSNER et al (US 6,706,726), in view of OHSHIMA, et al (US 6,514,996).

MEISSNER et al teaches the compound of the instant formula 1b from claim 4, which also reads on formula 1 from the instant claim 1 (see claim 1, where R1&2 are

C₁-alkyl, A is:, R3-6 are H, and R7 is C₁-alkyl). MEISSNER et al further

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teaches the use of the active ingredients for the treatment of respiratory tract diseases, such as asthma (claim 6) as well as the administration by inhalation solutions, suspensions or capsules (column 4 lines 3-9) when combined with common excipients (claim 8) and the addition of active substances, such as PAF-antagonists (claim 9).

MEISSNER et al does not teach the addition of the instant compound of formula 2 or specific ranges.

OHSIMA, et al teaches the use of the instant compound of formula 2 (see compound 140 at column 67 lines 1-15 and lines 50-55) for the use in treating asthma (column 294 lines 36-39) by administration through inhalation solutions, suspensions or capsules when combined with common excipients (see preparation examples 1-13 from column 292 line 5 to column 294 line 32). Additionally, OHSIMA et al teaches the compound exhibits PDE inhibition (column 294 lines 36-39).

Here, it would be obvious to one skilled in the art to follow the teaching of MEISSNER et al to add a PDE inhibitor to the compound disclosed for the treatment of asthma, taught by both references.

Additionally, it is prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation. See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955); *In re Boesch*, 205 USPQ 215 (CCPA 1980); and *In re Peterson*, 65 USPQ2d 1379 (Fed. Cir. 2003).

Conclusion

No claims allowed

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 9-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3 October 2007
BP


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER